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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,282

08/22/2006

Richard Soltero

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

10/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,282	Applicant(s) SOLTERO, RICHARD	
	Examiner MICAH-PAUL YOUNG	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/22/06, 6/1/09</u> . | 6) <input checked="" type="checkbox"/> Other: <u>WO01/01789</u> . |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 8/22/06 and 6/1/09 were filed in a timely manner. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claim 26 objected to because of the following informalities: Claim 26 is misnumbered as 26 an independent claim after claim 26, a claim dependent from claim 25. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5-16, 19-21 and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Roos et al (USPN 5,840,338 hereafter '338).

The '338 patent teaches an oral gel formulation comprising a gelatinous formulation (col. 4, lin. 1-8) comprising various gel forming polymers such as hydroxypropylcellulose, hydroxypropylmethylcellulose and polyethylene oxide (col. 4, lin. 26-35). The gel swells upon absorbing water (col. 43, lin. 45-63). The gel also can include pectin, agar and hyaluronic acid (col. 41, lin. 6-17). Pharmaceutically active agents are loaded into the gel network (col. 4, lin. 35-45). Included in the formulation are vitamins such as B12 (col. 9, lin. 65-col. 10, lin. 5),

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aspirin and ibuprofen, compounds useful for treating analgesia (col. 22, lin. 20-col. 23, lin. 40).

The gel includes buffers that adjust the pH (col. 60, lin. 35-38) and perfumes for aesthetic purposes (col. 61, lin. 1-10). These disclosures render the claims anticipated.

Claims 1, 2, 4, 5, 12-14, and 19-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Cherukuri et al (USPN 6,482,465 hereafter '465).

The '465 patent teaches an oral dosage form comprising various gelatinous matrix materials (abstract). The dosage forms comprises type B gelatin with a bloom of 250, and vitamin B complex (Table 9). The formulation comprises plant extracts such as ginseng and St. John's Wart (col. 13, lin. 24-35). The formulation includes olfactory compounds such as flavors and sweeteners flavors (col. 9, lin. 10-45). The formulation further comprises analgesics as well as prescription and non prescription active agents such as anti-tumor and cancer treating agents and acetaminophen (col. 10, lin. 50-col. 11, lin. 5). The formulation further comprises a small concentration of water (Table 2). Regarding the variable thickness limitation of the instant claims, it is the position of the Examiner that the dosage form of the '465 patent would inherently meet this limitation by teaches a dosage form with the same components and the instant claims. The claims requires an active agent, water and a hydrogel forming component. The '465 patent discloses such a formulation. Sweeteners are added to mask the taste of active agents, yet they are not necessarily delivered to the mouth. Since a composition and its properties cannot be separated, and a compositions properties are a result of its components, if a composition has the same components as a another they should also have the same properties. As such the '4components has the same components applied the same way and would inherently

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have the same viscosity properties as the instant claims. For these reasons the claims are anticipated by the prior art.

Claims 1, 2, 13-20, 23 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Ananthraman et al (WO 01/01789 hereafter '789).

The '789 patent teaches an oral formulation comprising an active agent and a gelatinous components in the form of a gel that is useful in delivering active agents to a pediatric patient suffering from dysphagia (abstract, pg 1, lin. 5-10). The composition is of a variable thickness, in the form of a pudding depending on the mixture with a viscosity from 4000-5000 cps (pg 3, lin. 20-30, pg 6, lin. 8-16). The gel comprises vitamin and proteins, including vitamin B12 (pg 5). The formulation also comprises a pH modifying components that balances the flavor as well (pg 6, lin. 1-10). These disclosures render the claims anticipated.

Claims 1-3, 5, 12-20 and 23 rejected under 35 U.S.C. 102(b) as being anticipated by Donnelly et al (USPN 3,904,771 hereafter '771).

The '771 patent teaches a gelatinous formulation comprising type A gelatin with a Bloom of 180 (col. 2, lin. 40-50, example 2). The gelatin is cold water soluble and is included in various dosage forms including easily swallowed desserts such as ice cream and pudding (Example 2). The formulation comprises buffers that chemically adjust the pH (col. 3, lin. 20-25). The formulation further comprises non prescription medicaments such as vitamin C along with olfactory and flavoring agents (col. 4, lin. 8-26). Regarding the administration of the dosage form to pediatric patients suffering dysphagia, it is the position of the Examiner that the

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cold dessert preparations of the '771 would inherently be useful in such a method since the only method step is administration and gelatin based puddings are well established as dosage forms used in pediatric medicine. The cold-water soluble gelatin based desserts of the '771 patent comprising vitamins established would inherently meet the limitations of administering active agents to pediatric patients since they are delivered to patients in need thereof And comprise the identical components of the instant claims. These compounds aid in the flavor and acceptance of the gelatinous dosage form aiding in swallowing. disclosures render the claims anticipated.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAHA-PAUL YOUNG/
Examiner, Art Unit 1618